ARM TYPE FULLY AUTOMATIC DIGITAL BLOOD PRESSURE MONITOR

OMEGA

INSTRUCTION MANUAL
MODEL: BSP-11

2014.01

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Safety Notice

Thank you for purchasing the BSP-11 Blood Pressure Monitor.
This unit has been carefully constructed using reliable circuitry and durable materials, designed to bring years of accurate results and satisfactory performance when used properly.

This device is intended for non-invasive measuring an adult individuals systolic, diastolic blood pressure and heart rate using the oscillometric method. The device is not intended for use on infants and children. The device is designed for home or clinical use. All results can be read on one LCD display screen. Measurements are to be taken from the upper arm of the adult.

Please read this manual thoroughly before using the unit. Please retain this manual for future reference. For specific information about your blood pressure, please consult your doctor or health care professional.

To avoid risks and damages please follow all warning precautions. Operate the unit only as intended. Read all instructions prior to use.

WARNING SIGNS AND SYMBOLS	
⚠	Caution
❗	Mandatory
⃠	Prohibited
	Type BF Equipment
	Consult Instructions For Use
SN	Serial Number
	Discard the used product to the recycling collection point according to local regulations
CE 0197	The product conforms to the requirements of the EC Directive MDD(93/42/EEC) on medical devices
	Manufacturer
EC REP	Authorized Representative in the European Community

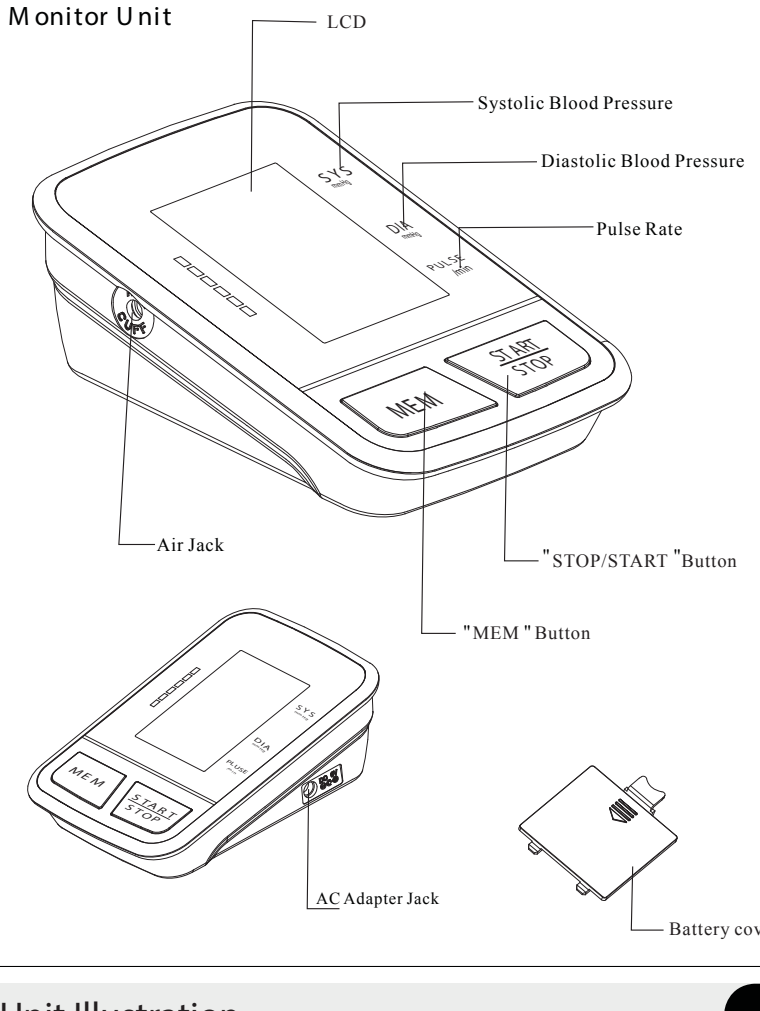
Safety Notice

⚠ Caution	
Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.	
Contact your physician if test results regularly indicate abnormal readings. Do not attempt to self-treat these symptoms without consulting your physician first.	
Product is designed for its intended use only. Do not misuse in any way.	
Product is not intended for infants or individuals who cannot express their intentions.	
Do not disassemble or attempt to repair.	
Do not use cell phones and other devices, which generate strong electrical or electromagnetic fields, near the device, as they may cause incorrect readings and interference or become interference source to the device.	
Only use a recommended AC adapter complying with EN 60601-1 and EN 60601-1-2（see page 6). An unauthorized adaptor may cause fire and electric shock.	

⚠ Battery Precautions
Do not mix new and old batteries simultaneously.
Replace batteries when Low Battery Indicator " " appears on screen.
Be sure battery polarity is correct.
Do not mix battery types. Long-life alkaline batteries are recommended.
Remove batteries from device when not in operation for more than 3 months.
Dispose batteries properly; observe local laws and regulations.

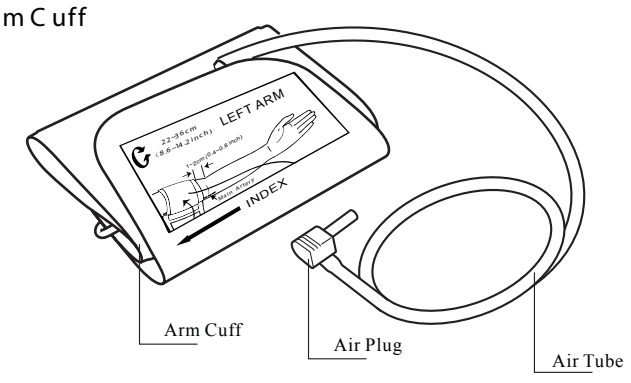
Unit Illustration

Monitor Unit

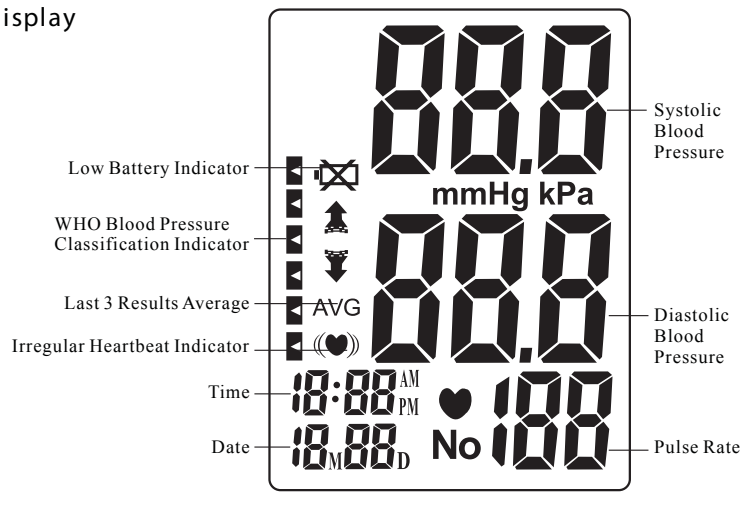


Unit Illustration

Arm Cuff

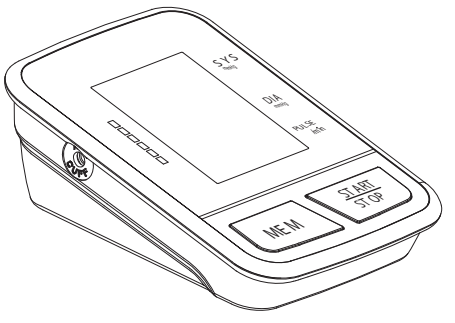


Display



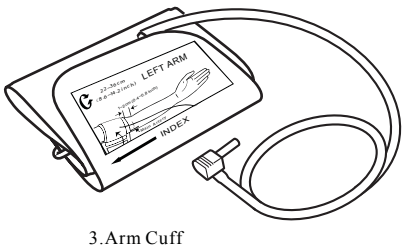
Unit Illustration

Contents

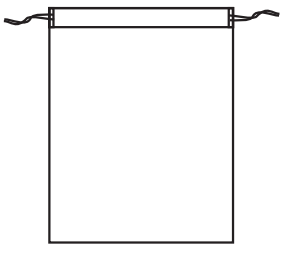


1.Monitor Unit

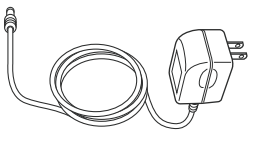
2.Owner's Manual



3.Arm Cuff



4.Storage Bag



5.Medical AC Adapter(DC6.0 V, 600mA)
(recommended, not provided)

Important Testing Guidlines

1. Avoid eating, exercising, and bathing for 30 minutes prior to testing.
2. Sit in a calm environment for at least 5 minutes prior to testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your arm level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid strong electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure at the same time each day for consistency.
8. Test comparisons should only be made when monitor is used on the same arm, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

Quick Start

1. Install batteries. (See Figure A)
2. Insert cuff air plug into the left side of monitor unit. (See Figure B)

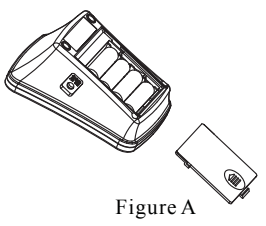


Figure A

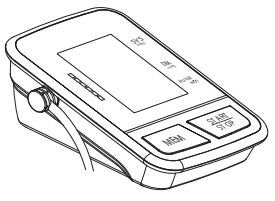


Figure B

3. Remove thick clothing from the arm area.
4. Rest for several minutes prior to testing. Sit down in a quiet place, preferably at a desk or table, with your arm resting on a firm surface and your feet flat on the floor. (See Figure C)

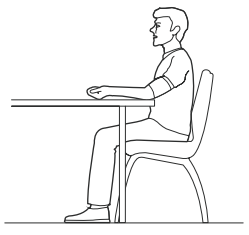


Figure C

5. Apply cuff to your left arm and keep level with your heart. Bottom of cuff should be placed approximately 1-2cm (0.4-0.8") above elbow joint. (See Figures D&E)

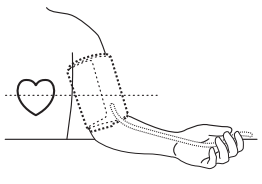


Figure D

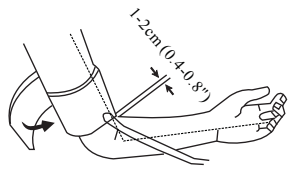


Figure E

6. Press "START/STOP" Button to start testing.

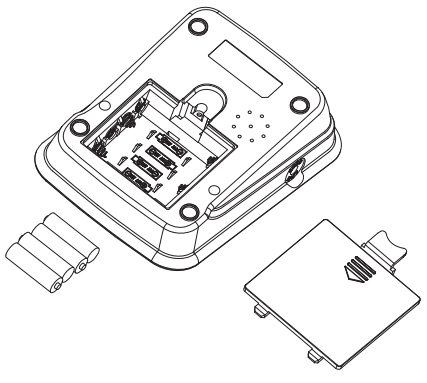
Unit Operation

Battery Installation

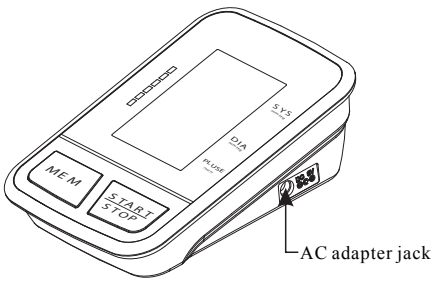
Slide battery cover off as indicated by arrow.

Install 4 new AAA alkaline batteries according to polarity.

Close battery cover.



AC adapter jack is on the right side of the monitor. Medical AC adapter(DC 6.0 V, 600mA) can be used with the device (recommended, not provided). The adapter connect pin should be positive inside and negative outside with a 2.1mm coaxial joint.
Do not use any other type of AC adapter as it may harm the unit.

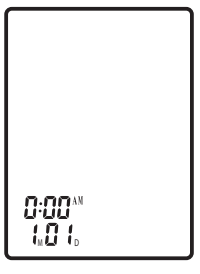


Unit Operation

Time/Date Setting

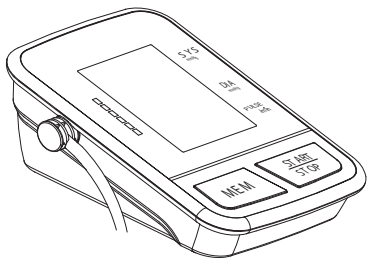
With power off, press “START/STOP ” button about 3 seconds to set the Time/Date mode. Set month first by adjusting the “MEM” button, Press “STOP/START ” button to set the day, hour, and minute in same way.
No matter in which setting mode, press“START/ STOP”button to turn the unit off.
All information will be saved.

Note: if unit is left on and not in use for 3 minutes, it will automatically save all information and shut off .

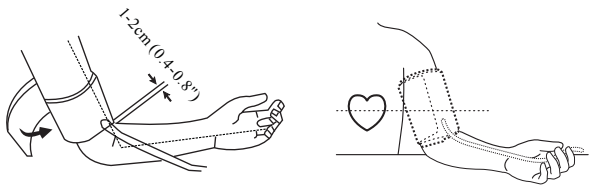


Applying the Arm Cuff

1. Firmly insert air plug into opening located on left side of monitor unit.



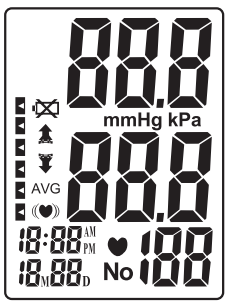
2. With sticky nylon section facing outward, insert end of cuff underneath metal ring of cuff.
3. Fasten cuff about 1-2cm (0.4-0.8") above the elbow joint. For best results apply cuff to bare arm and keep level with heart while testing.



Note: Do not insert air plug into opening located on right side of monitor unit. This opening is designed for an optional power supply only.

Testing

1. Power On
   Press and hold " START/STOP " button until a beep sounds. The LCD screen will appear for one second as unit performs a quick diagnosis. A long tone indicates device is ready for testing.



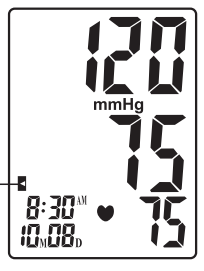
Note: Unit will not function if residual air from previous testing is present in cuff. The LCD will flash " " until pressure is stabilized.

2. Pressurization
   Initial pressure is first pumped to 190 mmHg. If the current user's systolic blood pressure is over 190mmHg, the unit will automatically re-inflate to the proper shelf.

3. Testing
   After cuff inflation, air will slowly subside as indicated by the corresponding cuff pressure value. A flashing " " will appear simultaneously on screen signaling heart beat detection.

Note: Keep relaxed during testing. Avoid speaking or moving body parts.

4. Result Display
   Three short beeps sound when testing is complete. The screen will display measurements for systolic and diastolic blood pressure.



Note: Refer to Page 18~19 for detail WHO Blood Pressure Classification Information

Irregular Heartbeat Indicator
If the monitor detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol " " "appears on screen along with measurement results. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol " " frequently appears with your test results.

5.Storing Test Results
It will automatically store by date .If the number of tests surpasses the allotted 120 memories , the most recent tests will appear first , thus eliminating the oldest readings.

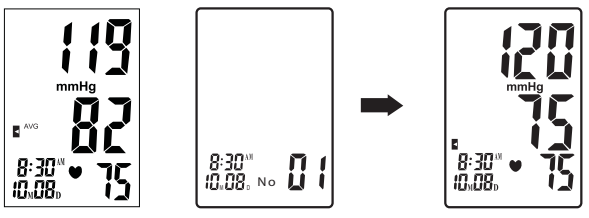
Power Off

The " START/ STOP" button can be pressed to turn off the unit in any mode. The unit can turn off the power itself about 3 minutes if no operation in any mode.

Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the " START/STOP " button to turn power off. The cuff pressure will rapidly dissipate once the unit is off.

Memory Check

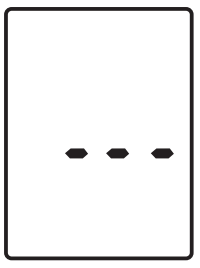
With power off, press and hold "MEM "button to turn the unit on. The LCD will display the average test results from the last 3 readings.Press "MEM "button again,the LCD will display the last measurement memory as NO: 01 reading . Older test result in memory can be viewed by pressing the"MEM"button.



Note: If the memory is less than 3 groups , press the "MEN" button to display the last group.

Memory Deletion

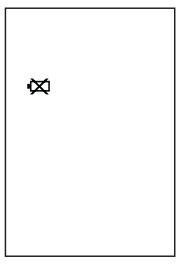
While in memory check mode. Press " START/ STOP" and hold on for about 3 seconds to delete all history results and the LCD screen display "- - -" with beep sounds. Then press " START/ STOP" button to turn off the unit.



Note: Memory cannot be recovered once it has been deleted.

Low Battery Indicator

4 short warning beeps sound when battery life is depleting and unable to inflate cuff for testing. The " " appears simultaneously for approximately 5 seconds prior to shutting off. Replace batteries at this time. No memory loss will occur throughout this process.



Troubleshooting

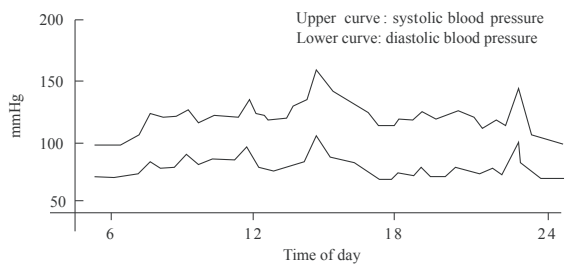
Problem	Possible Cause	Solution
Blood pressure results are not within typical range	Cuff is too tight or not properly positioned on the arm	Firmly reposition cuff approximately1-2cm (1/2") above the elbow joint (See Page 11)
	Inaccurate test results due to body movement or monitor movement	Sit in a relaxed position with arm placed near heart. Avoid speaking or moving body parts while testing. Make sure the monitor unit is placed in a stationary position throughout the testing period. (See Page 8)
" Err "displayed	Cuff fails to inflate properly	Make sure hose is properly fastened to cuff and monitor unit
	Improper operation	Read user manual carefully and re-test properly.
	Pressurization is over 300mmHg	Read user manual carefully and re-test properly.

Blood Pressure

Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimeters of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats.

An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure.

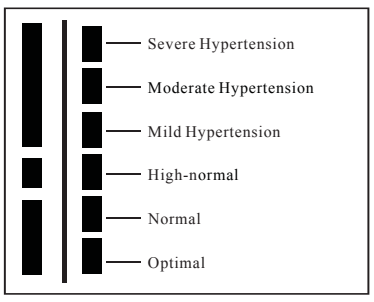
If these measuring numbers become too high, it means the heart is working harder than it should.



Example: fluctuation within a day (male, 35 years old)

WHO Blood Pressure Classification Indicator

The BSP-11 is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (color coded on monitor unit) indicates test results.

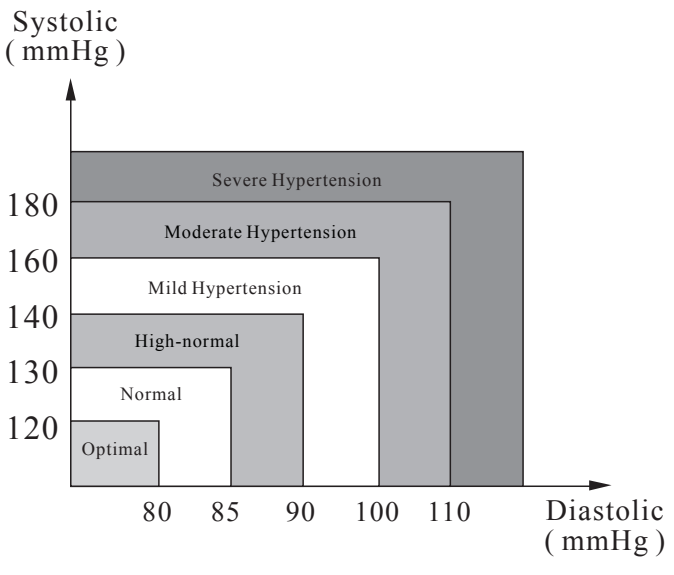


Mild Hypertension

: Blood Pressure Classification Indicator

Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to a lot of problems including heart failure, kidney failure, and cerebra haemorrhaging By maintaining a healthy lifestyle and visiting your physician on a regular basis, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. A better indication of an individual's blood pressure occurs after 2-3 readings are taken at the same time each day over an extended period of time. Consult your physician if test results remain abnormal.

Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?

A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

Note: Abnormal test results may be caused by:

1. Improper cuff placement
   Make sure cuff is snug-not too tight or too loose.
   Make sure bottom of the cuff is approximately 1-2cm (1/2") above the elbow joint.
2. Improper body position
   Make sure to keep your body in an upright position.
3. Feeling anxious or nervous
   Take 2-3 deep breaths, wait a few minutes and resume testing.

Q: What causes different readings?

A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc. may affect an individual's blood pressure.

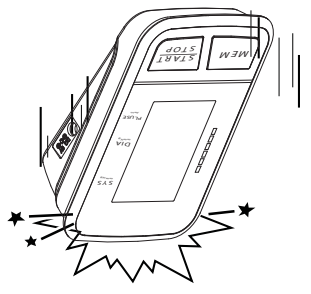
Q: Should I apply the cuff to the left or right arm? What is the difference?

A: Either arm can be used when testing, however, when comparing results, the same arm should be used. Testing on your left arm may provide more accurate results as it is located closer to your heart.

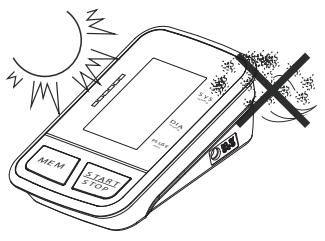
Q: What is the best time of day for testing?

A: Morning time or any time you feel relaxed and stress free.

1. Avoid dropping, slamming, or throwing the unit.

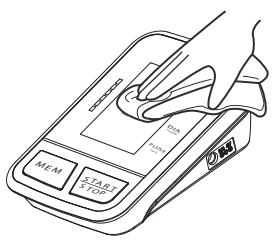


2. Avoid extreme temperatures. Do not expose unit directly under sunshine.



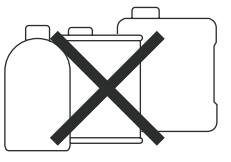
3. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent.

   Use a damp cloth to remove dirt and excess detergent.

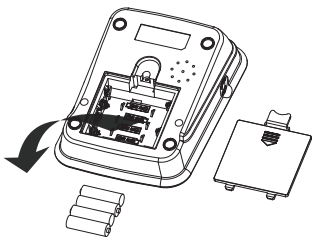


4. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature.

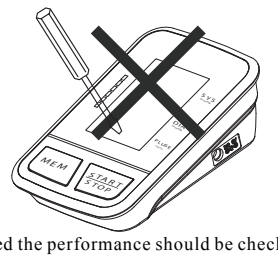
5. Do not use petrol, thinners or similar solvents.



6. Remove batteries when not in operation for an extended period of time.



7. Do not disassemble product.



8. It is recommended the performance should be checked every 2 years.

9. Expected service life: Approximately three years at 10 tests per day.

Product Description	Arm-type Fully Automatic Digital Blood Pressure Monitor	
Model	BSP-11	
Display	LCD Digital Display Size: 62.7mm×46.4mm (2.47" x 1.83")	
Measurement Method	Oscillometric Method	
Measurement Range	Pressure	0mmHg～300mmHg
	Pulse	30 to 180 Beats/Minute
Measurement Accuracy	Pressure	±3mmHg
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	120 Memories	
Function	Low Battery Detection	
	Automatic Power-Off	
Power Source	4 AAA batteries or Medical AC Aadapter(DC6.0V, 600mA) (recommended, not provided)	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx.360g (12.7oz.) (excluding battery)	
Unit Dimensions	Approx.140 x 98 x 48mm (5.51" x 3.86" x 1.89")(L x W x H)	
Cuff Circumference	Approx.135 (W)×485(L) mm (Medium cuff: Fits arm circumference 22-36 cm)	
Operating Environment	Temperature	10℃～40℃ (50℉~104℉)
	Humidity	15%~90%RH
	Pressure	Atmospheric Pressure

Storage Environment	Temperature:	-20℃~55℃ (-4℉~131℉)
	Humidity	15%~90%RH
Ingress Protection Rating:	IP 22	
Classification:	Internal Powered Equipment,Type BF ,Cuff is the Applied Part	

Specifications are subject to change without notice.

This Blood Pressure Monitor complies with the European regulations .This blood pressure monitor also complies with mainly following standards (included but not limited):
Safety standard:
EN 60601-1 Medical electrical equipment part 1: General requirements for safety
EMC standard:
EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility- Requirements and tests
Performance standards:
EN 1060-1 Non-invasive sphygmomanometers - General requirements
EN 1060-3 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.
EN 1060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

Correct Disposal of This Product
(Waste Electrical & Electronic Equipment)

This marking shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center.
Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

Warranty

The Blood Pressure Monitor is guaranteed from the date of purchase. If theBlood Pressure Monitor does not function properly due to defective components or poor workmanship, we will repair or replace it freely. The warranty does not cover damages to your Blood Pressue Monitor due to improper handling. Please contact local retailer for details.

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